Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

The effect of effleurage massage and foot reflexology training on quality of life in patients with multiple sclerosis

Protocol summary

Study aim
Determining the effect of Effleurage massage and reflexology training on the quality of life of patients with MS

Design
a two-arm parallel-group randomized trial with accidental 45 participants by the Random number table

Settings and conduct
The study site is in Qom and, the study will include three groups of Effleurage, reflexology, and control for eight weeks and three times a week.

Participants/Inclusion and exclusion criteria
Participants in the study of patients with multiple sclerosis 18 years and older in both men and women who have equal or higher pain and fatigue scores of 4 and an Expanded disability scale of 2-6 and are willing to participate in the study.

Intervention groups
In the Effleurage massage group, using two drops of sweet almond oil, the Effleurage massage will be done by the caregiver in the thigh and hip muscles and leg and sole for 10 minutes on each leg. In the foot reflexology group: reflective points on the head, neck, solar plexus, pelvis, shoulders, pituitary gland, hip, adrenal glands, which will be marked by a marker on the sole, by the index finger and thumb, deep pressure 2-3 mm, the intended time for pressing the reflecting points for each foot will be 10 minutes. Control group: Members of this group will lubricate each sole for 10 minutes with emollient ointment, so the length of each session in these three groups will be 20 minutes.

Main outcome variables
Pain, fatigue, ability to walk, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210723051959N1**
Registration date: **2021-09-06, 1400/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-06, 1400/06/15**
Update count: **0**

Registration date
2021-09-06, 1400/06/15

Registrant information

Name
Fatemeh Akbari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 25 3784 6180

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-22, 1400/05/31

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of effleurage massage and foot reflexology training on quality of life in patients with multiple sclerosis

Public title

The effect of effleurage massage and foot reflexology training on quality of life in patients with multiple sclerosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with MS, in the age group of 18 years and older, are members of the Qom MS Association and please to participate in this study. Fatigue score equal to or Greater than four according to Fatigue Severity Scale Pain score equal to or Greater than four, according to the Analogue Visual Scale (Vas) Extensive disability score 2-6 according to the Expanded Disability Status Scale Ability to walk comfortably at least 10 meters, with support if needed Ability to stand for at least 60 seconds, with an attendant if needed patients who have not used complementary therapies in the last six months patients who are not prohibited from massage and do not have wounds and skin problems that interfere with the message those who do not have fractures, thrombosis, and arthritis in the foot area No drug addiction

Exclusion criteria:
Pregnancy and taking it during the study Inability to massage by the companion hypotension, unstable cardiovascular conditions If the patient informs the researcher that they used Analgesics or antidepressants during the study, will be excluded them History of hypothyroidism Neuromuscular diseases

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of 45 patients in use according to inclusion and exclusion criteria, randomly into three intervention and control groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Qom University of Medical Sciences

Street address
No. 83, 1/1 Alley, Safashahr St, Qom town

City
Qom

Province
Ghoum

Postal code
93456-37169

Approval date
2021-07-13, 1400/04/22

Ethics committee reference number
IR.MUQ.REC.1400.063

Health conditions studied

1

Description of health condition studied
multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Disseminated Multiple Sclerosis

Primary outcomes

1

Description
quality of life

Timepoint
Before the intervention and at the end of the Study

Method of measurement
MSQOL-54(Multiple Sclerosis Quality of Life-54)

Secondary outcomes

1

Description
Pain score

Timepoint
Before the intervention, after each intervention session, at the end of the study

Method of measurement
Visual analogue scale

2

Description
Fatigue score

Timepoint
Before the intervention, after each intervention session, at the end of the study

Method of measurement
Fatigue Severity Scale

3

Description
Walking speed
Timepoint
Before the intervention and at the end of the study
Method of measurement
Timed 25-Foot Walk

4

Description
Fatigue score
Timepoint
Before the intervention and at the end of the study
Method of measurement
Fatigue Impact Scale

Intervention groups

1

Description
Effleurage massage will be performed in the patient's home and place suitable in terms of humidity and heat by the caregiver. Effleurage massage with two Drops of Sweet almonds oil will be done for 10 minutes on each leg to prepare the person and create relaxation in the thigh and hip muscles and calf and sole muscles. Effleurage massage will include slow, rhythmic, and gentle movements, usually blood flow to the heart. And a superficial pressure will be applied by the palm to the skin of the patient's body during reciprocating movements, so the total duration of the session will be 20 minutes
Category
Rehabilitation

2

Description
Intervention group 2: in the Reflexology group, using a silicone marker, reflective points on the head, neck, solar plexus, pelvis, shoulders, pituitary gland, hip, adrenal glands, On the sole, by the index finger and thumb, pressure with a depth of 2-3 mm and regular rhythm and round and approaching the two toes and pointing will be done at the point of reflection, the time allotted for the pressure of the reflective points for each The foot will be 10 minutes, so the total duration of the massage in each session will be 20 minutes. Then the FSS fatigue score will be measured by the caregiver immediately after each session and, the pain scores one hour and, the results will be sent to the researcher via SMS by the caregiver.
Category
Rehabilitation

3

Description
Control group: to simulate the processes performed in the intervention groups, will lubricate each sole with emollient ointment for 10 minutes 3 times a week for eight weeks, so the length of Each session in this group will be 20 minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Association of Patients with Multiple Sclerosis in Qom
Full name of responsible person
Fakhruddin Hejazi
Street address
27th Alley, Honarestan st, Qom
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
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research@mail.muq.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic

Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Mahsa Haji Mohammad Hosseini
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Information about the original and secondary consequence
When the data will become available and for how long
6 months after accepting of article
To whom data/document is available
Researchers working at the university and scientific institutions
Under which criteria data/document could be used
Requires data to do similar research
From where data/document is obtainable
Fatemeh Akbari: fafa_ak@yahoo.com Mahsa Haji Hosseini: MAHSA.NMSPRG@GMAIL.COM
What processes are involved for a request to access data/document
Email / Check the reason for content request and file / approval by the executive and colleagues / send the file
Comments